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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,535	05/31/2000	Jean-Christophe Francis Audonnet	454313-2335.1	6015

20999 7590 08/27/2003

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EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	19

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/586,535	AUDONNET ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13,15-24,28-35,37,39-51 and 54-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,15-24,28-35,37,39-51 and 54-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

The Amendment and Remarks filed on 6/12/03 have been entered as Paper #18. Claims 12, 13, 20, 24, 40, 41, 47, and 51 have been amended. Claims 25, 26, 51, 52, 53, 67, and 68 have been canceled. It is noted that the numbers of the canceled claims are inconsistent in page 4 and page 5 of paper #18, and claim 51 has been indicated as being amended (page 4) and cancelled (page 5), further clarification is necessary in the response to this Office action. For the interest of compact prosecution, claim 51 has been treated as pending. Claims 12, 13, 15-24, 28-35, 37, 39-51, and 54-66 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims and arguments will not be reiterated. The amendment necessitates the modification of the standing rejection. The arguments in paper #18 would be addressed to the extent that they apply to current rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The prior rejection of claims 12, 15-24, 28-35, 37, 39, 40, 42-51, and 54-66 has been modified under 35 U.S.C. 103(a) as being unpatentable over *Poet et al* (US

6,217,883), and *Meehan et al* (J Gen Virol 1998;79:2171-79), in view of *Nabel et al* (US 5,910,488).

The amended claims 12, 40, 47 are now drawn to an immunogenic preparation comprising at least one plasmid encoding and expressing an ORF derived from *PCV-2* only, rather than both PCV-1 and PCV-2. The amended claims 24 and 51 recited "at least two plasmid" rather than "at least one plasmid".

In paper #18, applicants argue that Poet et al relates to DNA vaccines against beak and feather disease virus (BFDV) and/or PCV-1, does not teach or suggest a DNA vaccine encoding and expressing PCV-2. One cannot extrapolate from the teachings of Poet et al to the instant invention because a vaccine derived from BFDV or PCV-1 would not be effective against PCV-2.

The argument has been fully considered but they are not persuasive for reasons of record in papers #14, 16, and following.

First, the arguments are contradictory to the teaching of the original claims and disclosure, wherein PCV-1 and PCV-2 are included in the same Markush group. In the specification, both plasmids expressing PCV-1 and PCV-2 are considered as the preferred embodiment of the invention (e.g. Specification, page 5, lines 34-39; and figures 1-4). Therefore, the original disclosure teaches that both PCV-1 and PCV-2 are effective immunogenic preparation.

Second, although *Poet et al* do not teach the sequence of PCV-2, they clearly teach the correlation of PCV and pig wasting syndrome (column 1, lines 57-65). *Meehan et al* clearly teach that PCV-2 rather than the classic PCV-1 is more closely

associated with pig wasting syndrome (abstract). They go on to teach that the structural similarities and differences between PCV-1 and PCV-2, particularly with regard to the ORF1 and ORF2 region, and concluded "THE PORCINE CIRCOVIRUSES ASSOCIATED WITH WASTING SYNDROMES IN PIGS (PCV-2) WERE ANTIGENICALLY DISTINCT FROM THE PCV PK-15 CELL CULTURE ISOLATE (PCV-1)" (2nd paragraph, page 2178, notes added). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Poet et al*, by simply substituting or including PCV-2 sequence when developing a vaccine for pig wasting syndrome as taught by *Meehan et al;* with a reasonable expectation of success. One of skilled in the art would have been motivated to do so, because *Meehan et al* teach that PCV-2 is more relevant antigen for PWSN, and thus, would be more effective vaccine *in vivo*. With regard to the numbers of plasmid used for expressing the recited ORFs, it is well known in the art that a plasmid has limited cloning capacity in size, and it is within the knowledge of ordinary skill to determine whether a particular sequence should be cloned in the same or a different plasmid depending on the size of the sequences to be cloned. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Poet et al*, *Meehan et al,* and *Nabel et al* by cloning the different ORF regions in more than one plasmid for efficient expression with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

The prior rejection of claims 13, 18-24, 37, 39, 41, 45-51, 65 and 66 has been modified under 35 U.S.C. 103(a) as being unpatentable over *Poet et al* (US 6,217,883) and *Meehan et al* (J Gen Virol 1998;79:2171-79), in view of *Mathiowitz et al* (US 6,475,779).

The amended claims 13, 41, 47 are now drawn to an immunogenic preparation comprising at least one plasmid encoding and expressing an ORF derived from PCV-2, rather than both PCV-1 and PCV-2. The amended claims 24 and 51 recited "at least two plasmid" rather than "at least one plasmid".

The arguments for this rejection were combined with the previous rejection; therefore, for the reasons set forth in the immediate preceding section, the rejection stands.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
August 18, 2003

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER